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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,294	12/19/2001	Suzie Hwang Pun	038134-5006	9341

28120 7590 09/10/2003
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EXAMINER

MAIER, LEIGH C

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/021,294	Pun
	Examiner	Art Unit
	Leigh Maier	1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-7 and 11-21 is/are pending in the application.

4a) Of the above, claim(s) 1-4 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 5-7 and 11-21 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on Dec. 19, 2001 is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) Interview Summary (PTO-413) Paper No(s). 4
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

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DETAILED ACTION

Election/Restriction

Applicant's election with traverse of Group II in Paper No. 11, filed June 24, 2003 is acknowledged.

The traversal is on the ground(s) that the claims depend from the claims of Group I, so that the examination of the claims of Group I would require no further search. This is not found persuasive because in searching the complexing agents of Group II, the search includes ones in which combining with the other required components recited in the claim would be anticipated or obvious. A search solely for the compounds of Group I, particularly directed to non-obvious compounds, would require consideration of other reasons for preparing said compounds, not restricted to their utility in combination with said other components. Therefore, a search of these compounds would not be co-extensive with the search of Group II. The requirement is still deemed proper and is therefore made FINAL.

In accordance with the election of species requirement, Applicant has selected Ad-PEG-Tf as the complexing agent, and nucleic acids as the class of therapeutic agents. This has been searched along with a larger genus carved out around this species and has been found free of the art, as will be discussed further below. The next species for searching has been selected by the examiner, also discussed below.

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Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 5, 6, 12, 13, and 19 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by KOSAK et al (US 6,048,736).

KOSAK discloses a composition comprising a CD polymer, a complexing agent, (2-aminoanthracene) and an antibody. See preparation IV.

This species does not read on claims 7, 14-18, 20, and 21, and these claims have been withdrawn from consideration.

Double Patenting

Claims 5-7 and 11-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-20 of copending Application No. 10/021,312. Although the conflicting claims are not identical, they are not

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patentably distinct from each other because the composition recited in the claims of copending '312 comprises a narrower set of components anticipating the instant compositions.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

As stated above, the elected species, Ad-PEG-Tf as the complexing agent, and nucleic acids as the class of therapeutic agents has been searched and found free of the art. The search was expanded to include a composition comprising:

- (1) a CD-containing polymer;
- (2) a therapeutic agent; and
- (3) adamantanyl-PEG(including branched and additional linkers)-functional group.

In this composition, the "therapeutic agent" and "functional group" are generic. A claim drawn to such a composition would be allowable. The following is a statement of reasons for the indication of allowable subject matter: AMIEL et al (Adv. Coll. Int. Sci., 1999) teaches the preparation of Ad-PEG-Ad in combination with CD-containing polymers. See, for example, abstract and page 108. The reference does not teach or fairly suggest the substitution of one of the Ad-moieties with any other functional group. Nor does the reference teach or suggest the addition of a therapeutic agent. GONZALEZ et al (Bioconj. Chem., 1999) teaches CD-containing

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polymers in combination with nucleic acids. The reference does not teach or fairly suggest the addition of a complexing agent as recited in the instant invention.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (703) 308-4525. The examiner can normally be reached on Monday-Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (703) 308-4624, may be contacted. The fax phone number for Group 1600, Art Unit 1623 is (703) 308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.



Leigh C. Maier
Patent Examiner
September 8, 2003